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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,390	10/25/2005	Virginie Louvain	263989US0PCT	2517

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EXAMINER	
TSAY, MARSHA M	

ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
07/24/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/518,390	LOUVAIN ET AL.	
	Examiner	Art Unit	
	Marsha M. Tsay	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *4,23-30,36 and 37* is/are withdrawn from consideration.

5)☒ Claim(s) *3 and 18-22* is/are allowed.

6)☒ Claim(s) *1,2 and 5-17* is/are rejected.

7)☒ Claim(s) *31-35 and 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02.18.05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's election with traverse of Group I, claims 1-3, 5-22, to SEQ ID NO: 9, in the reply filed on April 25, 2008 is acknowledged. The traversal is on the ground(s) that claims 1 and 4 share the common technical feature described in SEQ ID NO: 31, namely the thrombin-cleavable sequence Pro-Arg-Ala at the activation site. This is not found persuasive because as noted in the restriction requirement of December 12, 2007, Groups III-IV are drawn to factor Xa analogues, which can be selected from factor X analogues and/or factor X analogue analogues, while Group I is drawn to a factor X analogue, which is structurally different than said analogues of Groups III-IV. It is noted that claim 9 was not included in any of the original groups and is included in the elected claims for examination.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4, 23-30 have been withdrawn from further examination by the Examiner because they are drawn to non-elected inventions. Claims 31-38 are newly presented. Claims 31-35, 38 are within the scope of the elected claims. Claims 36-37 are not required to be included with the elected claims because Group I already has a method of using said analogue. Claims 1-3, 5-22, 31-35, 38, to SEQ ID NO: 9, are currently under examination.

Priority: Applicants have claimed foreign priority to July 3, 2002.

Specification

The disclosure is objected to because of the following informalities: on page 1 of the specification, the priority data needs to be updated with a cross-reference paragraph to related applications.

Appropriate correction is required.

Claim Objections

Claims 1-3, 5-22 are objected to because of the following informalities: claim 2 is objected to because it recites sequences encompassed by SEQ ID NO: 31 that are not elected. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2, lines 3-4, P_3 represents any amino acid. It is unclear what is meant if "any amino acid" includes both naturally and/or unnaturally occurring amino acids. Further clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an

international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 8, 11-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Himmelspach et al. (US 6573071). Himmelspach et al. teach a Factor X analogue having a processing site for a protease other than trypsin, Factor IXa, Factor VIIa, said analogue comprising a Factor X amino acid sequence wherein amino acids Gly228 to Ile235 have the sequence of Gly228-R6-R5-R4-R3-R2-Arg234-R1, wherein

a) R1 is an amino acid selected from the group consisting of Ile, Val, Ser, Thr, and Ala,

b) R2 is an amino acid selected from the group consisting of Pro, Gly, Lys, and Arg,

c) R3 is an amino acid selected from the group consisting of Phe, Lys, Met, Gln, Glu, Ser, Val, Arg, and Pro

d) R4 is an amino acid selected from the group consisting of Asp, Ile, Ser, Met, Pro, Thr, Arg, Lys,

e) R5 is an amino acid selected from the group consisting of Asn, Lys, Ser, Glu, Ala, Gln, His, and Arg, and

f) R6 is an amino acid selected from the group consisting of Asp, Phe, Thr, Arg, Leu, and Ser.

Therefore, Himmelspach et al. teach the sequence Gly228-Asp229-Asn230-R4-**Pro232-Arg233-Ile234**-Val235-Gly236, wherein the amino acids in bold correspond to the instant thrombin-cleavable sequence Pro-Arg-Ala (claims 1-2). Himmelspach et al. also teach a preparation comprising said Factor X analogue having a processing site as noted by the sequence noted above (col. 84 lines 60-67; claims 8, 15).

While Himmelspach et al. do not specifically teach a Factor Xa analogue, this analogue is within the scope of Factor X analogues disclosed by Himmelspach et al. (claims 11-14).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-7, 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Himmelspach et al. (US 6573071). The teachings of Himmelspach et al. are outlined above. Himmelspach et al. further disclose nucleic acid molecules, expression vectors, and host cells that can be used to express the Factor X analogues disclosed by Himmelspach et al. (col. 17-28). Himmelspach et al. do not explicitly teach a nucleic acid molecule encoding the thrombin-cleavable sequence Pro-Arg-Ala.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a Factor X analogue having the thrombin-cleavable sequence Pro-Arg-Ala as disclosed by Himmelspach et al. by constructing expression plasmids for the preparation of Factor X analogue for expression in host cells (claims 5-7, 12-14). The motivation to do so is given by Himmelspach et al., which disclose that Factor X analogues having the thrombin-cleavable sequence Pro-Arg-Ala can be prepared by constructing expression plasmids followed by transformation into a host cell for expressing a Factor X analogue protein.

Claims 9-10, 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Himmelspach et al. (US 6573071). The teachings of Himmelspach et al. are outlined above. Himmelspach et al. further disclose Factor X/Xa is an important component of the prothrombinase complex and may be used to treat patient suffering from blood coagulation disorders, i.e. hemophilia (col. 3-4). Himmelspach et al. do not explicitly teach a preparation comprising a Factor X analogue with the thrombin-cleavable sequence Pro-Arg-Ala.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the Factor X analogue of Hammelspach et al. to a patient for the treatment of hemophilia because Hammelspach et al. disclose Factor X/Xa which exhibits high stability and can be activated to Factor Xa without use of conventional proteases (col. 4 lines 30-35), i.e. modified to have the thrombin-cleavable sequence Pro-Arg-Ala, can be administered to treat patients suffering from hemophilia (claims 9-10, 16-17).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 31-35, 38 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 3, 18-22. When two claims in an application are duplicates or else are so close in content

that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 3, 18-22 appear to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

July 17, 2008